1. The drawings are objected to because in Figure 3, the word "Photocoagulation" is misspelled in the y-axis labels of both graphs. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

There is no copendency between the instant application and the provisional application recited in the claim for priority contained in the amendment filed March 25, 2003. Applicant's petition to correct the filing date of the instant application was dismissed in the decision mailed April 17, 2003.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 3-6, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156). The Grant et al abstract teaches treating diabetic retinopathy by administering a combination of octreotide and 100-200 μg/day thyroid hormone/levothyroxine.

5. Claims 7-13 are rejected under 35 U.S.C. 103(a) as being obvious over the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156). Application of the Grant et al abstract is the same as in the above rejection of claims 3-6, 17, and 18. The Grant et al abstract does not teach it active agents in kit form in syringes or oral dosage forms, and does not teach optimizing the relative dosages of the active agents. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the active agents of the Grant et al

abstract in kit form because it is routine in the pharmaceutical arts to provide active agents in kit form for ease of storage, transportation, measurement, and administration. It would further have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the active agents of the Grant et al abstract in the form of syringes or in oral dosage forms because these are conventional forms for administering pharmaceutical agents. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal dosages and relative dosages for the active agents of the Grant et al abstract because dosage is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

6. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156) as applied against claims 1-6, 17, and 18 above, and further in view of the Patel et al article (Endocrinology, Vol. 135, pages 2814-2817). The Grant et al abstract teaches using octreotide, but do not teach first characterizing the binding activity of the octreotide to the sstr2 receptor before their use. The Patel et al article teaches that it is known to characterize the binding activity of various somatostatin analogs, including octreotide, to various somatostatin receptors, including SSTR2 (see, e.g., Table 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to further characterize the binding activity of the octreotide of the Grant et al abstract to the sstr2 receptor, because the Patel et al article shows that this is a property of interest for the clinical use of somatostatin analogs, because it is routine in the pharmaceutical arts to characterize the chemical and physiological properties of therapeutic agents, and because the

results of such an assay would not affect the teaching of the Grant et al abstract that octreotide is actually useful in the treatment or prevention of diabetic retinopathy.

7. Applicant's arguments filed March 25, 2003 have been fully considered but they are not persuasive.

Applicant did not respond to the objection to the drawings set forth in paragraph 1 of the first Office action and repeated above.

As noted above, Applicant's petition to correct the filing date of the instant application was dismissed in the decision mailed April 17, 2003. Should Applicant's subsequent petition on this issue be granted, then there will be copendency between the instant application and provisional application 60/188,483, and instant claims 3-15 and 17 will be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of the parent provisional application because the parent provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention. Under such circumstances, the Grant et al abstract will remain prior art against the instant claims under 35 U.S.C. 102(a) because it was published less than one year before the provisional application was filed and is "by another". It would be possible for Applicant to antedate or overcome this reference, e.g., by submission of declarations under 37 CFR 1.131 or 132. Should Applicant's subsequent petition on this issue be granted, then there will be copendency between the instant application and provisional application 60/188,483, but instant claim 18 will not be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of the parent provisional application because the parent provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose administering thyroid related substances in general in amounts of 100-200 μg a day. While this dosage range is disclosed in the parent provisional

application for thyroxine specifically (see page 16, lines 19-20), there is no indication in the parent provisional application that this numerical dosage range applies to all thyroid related substances. Accordingly, even with copendency between the instant application and the parent provisional application, the Grant et al abstract will be available as prior art against instant claim 18 under 35 U.S.C. 102(b).

In the absence of a favorable decision on a petition to correct the filing date of the instant application, the Grant et al abstract remains prior art against all of the instant claims under 35 U.S.C. 102(b).

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

May 20, 2003